

UNITED STATES DISTRICT COURT
DISTRICT COURT OF MASSACHUSETTS

IN RE NEW ENGLAND COMPOUNDING)	
PHARMACY, INC. PRODUCTS LIABILITY)	MDL No. 2419
LITIGATION)	Dkt. No. 1:113-md-2419 (FDS)
)	

**HIGH POINT SURGERY CENTER'S MEMORANDUM IN SUPPORT OF ITS
OBJECTIONS TO THE PLAINTIFFS' STEERING COMMITTEE'S SUBPOENA**

COMES NOW Non-Party Respondent High Point Surgery Center and files its Memorandum in Support of its Objections to Plaintiffs' Steering Committee's Subpoena served on July 12, 2013. High Point Surgery Center shows the Court the following:

FACTUAL AND PROCEDURAL BACKGROUND

Because this Court is thoroughly familiar with the background of this multidistrict litigation ("MDL"), High Point Surgery Center will not, in the interest of judicial economy, recite the facts beyond providing a brief overview specific to the subpoena at issue.

High Point Surgery Center is a health care provider licensed by the State of North Carolina to operate an ambulatory surgery center in High Point, North Carolina. The Plaintiffs' Steering Committee (the "PSC") served a subpoena upon High Point Surgery Center by U.S. Mail on July 12, 2013 ("the Subpoena," attached hereto as "Exhibit A"). The Subpoena directed High Point Surgery Center to designate corporate representatives to appear for deposition and to produce documents, electronically stored information, and/or objects for inspection, copying, testing, or sampling at the deposition.

Among other Requests, the PSC directed High Point Surgery Center to produce the protected health information of each and every patient that was administered a New England Compounding Pharmacy ("NECP"), also known as New England Compounding Center, product. Specifically, Request 6 sought:

Any and all documents and/or ESI reflecting, and/or related to, the identification of each and every patient that was administered an NECP product during the five-year period immediately preceding October 6, 2012, including patient name, address, date of birth, identification of product administered, and date product was administered.

(Subpoena at Ex. B, ¶ 6)

On July 26, 2013, High Point Surgery Center objected to the PSC's Subpoena on several grounds, including that Request 6 exceeded the bounds of Federal Rule of Civil Procedure 26(b)(1), as the identity and other protected health information of non-party patients, who were treated by a non-party healthcare provider, was wholly irrelevant to the pending litigation and in violation of HIPAA. High Point Surgery Center objected further to the extent Request 6 sought information which was confidential and protected pursuant to North Carolina law.

Before High Point Surgery Center filed its objections, the PSC filed a "Consolidated Response to Subpoena Objections" in response to objections filed by other non-party healthcare providers who were served with subpoenas similar to the one served upon High Point Surgery Center by the PSC ("the Consolidated Response"). (The Plaintiffs' Steering Committee's Consolidated Response to Subpoena Objections, filed July 17, 2013, Dkt. No. 325.) In its Consolidated Response, the PSC limited the scope of Request 6 of those subpoenas to (1) lists of patients who received an injection of a medication lot that the Centers for Disease Control and Prevention ("CDC") determined was contaminated and (2) any lists of patients already compiled by a clinic in response to a request from any federal or state agency, any Grand Jury Subpoena, or any other governmental agency. (*Id.* at p. 6.)

The PSC claims to need this information for three purposes: (1) to establish or bolster its liability against NECC; (2) to understand the role clinics, doctors, and/or health care providers

played in the unfolding of the NECC-related debacle (including whether they or others share any liability); and (3) for providing actual notice of the bar date in the NECP's bankruptcy case to potential claimants. (*Id.* at p. 8.) Further, the PSC stated that identifying all known and reasonably ascertainable personal injury and wrongful death victims was among the most important objective in issuing the subpoenas to non-parties, such as High Point Surgery Center. (*Id.* at p. 15.) Thus, the protected health information of patients who are not clients of the PSC and have not consented to the release of their information will ultimately be used to notice patients who have not yet filed suit, and therefore, are not parties to this multidistrict litigation. (*See id.* at p. 25 fn. 74.)

High Point Surgery Center is informed and believes that the United States Bankruptcy Court for the Eastern District of Massachusetts has already heard arguments regarding how potential creditors, including patients who have not brought an action against NECP but who may have received MPA from the three lots at issue, may be identified and notified of their rights before the bar date in NECP's bankruptcy action. High Point Surgery Center further understands that the bankruptcy court has stated that it will require non-party healthcare providers to identify these patients and will create a process for notifying them. High Point Surgery Center is also informed that an order to that effect is in the process of being drafted by the bankruptcy court.

High Point Surgery Center, as a non-party to this litigation, maintains that PSC's Request for the protected health information of High Point Surgery Center's non-party patients goes far beyond the scope of legitimate discovery, pursuant to Federal Rule of Civil Procedure 26(b)(1). Further, to provide this information to the PSC would render High Point Surgery in violation of Health Insurance Portability and Accountability Act and the regulations enacted pursuant to the

Health Insurance Portability and Accountability Act (collectively “HIPAA”) and North Carolina’s patient privacy laws.

ARGUMENT

High Point Surgery Center understands that other entities have already thoroughly briefed the issues that (1) the PSC’s request for the identities and other protected health information of non-party patients is outside the scope of discovery allowed for subpoenas under Federal Rules of Civil Procedure 45 and 26 and (2) the PSC’s request is seeking non-party patients’ protected health information without their authorization and in violation of HIPAA. Accordingly, High Point Surgery Center will not address those issues here. High Point Surgery Center will focus only on the protection afforded to medical information by North Carolina law.

Contrary to the view of the PSC, compliance of HIPAA alone, which governs the confidentiality of protected health information, cannot satisfy North Carolina law, which imposes independent burdens and obligations. HIPAA does not preempt State law where “[t]he provision of State law relates to the privacy of individually identifiable health information and is more stringent than a standard, requirement, or implementation specification” contained in the HIPAA Privacy Rule. 45 C.F.R. §§ 160.203, 160.203(b).

Further, this MDL is comprised of state law tort claims, and thus, this Court should apply state law privileges. *See* Fed. R. Evid. 501; *Hottle v. Beech Aircraft Corp.*, 47 F.3d 106, 107n. 1 (4th Cir. 1995).

A. North Carolina’s Physician-Patient Privilege Strictly Limits the Disclosure of Patients’ Medical Information.

Federal Rule of Civil Procedure (45)(c)(3)(A)(iii) requires a court to quash or modify a subpoena that requires disclosure of privileged or other protected matter, when no exception or

waiver applies. North Carolina law regarding the release of patient health information is generally more stringent than the requirements of HIPAA and, accordingly, supersedes HIPAA's provisions.

Specifically, N.C. General Statute § 8-53, which sets forth the physician-patient privilege, provides that confidential information obtained in medical records may be furnished only upon the authorization of the patient (or in certain circumstances, the patient's legal representative) or upon the order of a judge in narrowly defined circumstances:

No person, duly authorized to practice physic or surgery, shall be required to disclose any information which he may have acquired in attending a patient in a professional character, and which information was necessary to enable him to prescribe for such patient as a physician, or to do any act for him as a surgeon, and no such information shall be considered public records under G.S. 132-1. Confidential information obtained in medical records shall be furnished only on the authorization of the patient, or if deceased, the executor, administrator, or, in the case of unadministered estates, the next of kin. Any resident or presiding judge in the district, either at the trial or prior thereto, or the Industrial Commission pursuant to law may, subject to G.S. 8-53.6, compel disclosure if in his opinion disclosure is necessary to a proper administration of justice. If the case is in district court the judge shall be a district court judge, and if the case is in superior court the judge shall be a superior court judge.

N.C. Gen. Stat. § 8-53 (2013) (emphasis added) (a copy of the North Carolina statutes and cases cited are attached hereto as "Exhibit B"). North Carolina courts have held that the physician-patient privilege applies to the clinical records of hospitals and other institutional providers. *See, e.g., Sims v. Charlotte Liberty Mut. Ins. Co.*, 257 N.C. 32, 125 S.E.2d 326 (1962).

The North Carolina courts have strictly limited the healthcare providers' ability to disclose health information subject to the privilege due to the fundamental importance of the confidentiality of the physician-patient relationship:

One of the objects of this statute is to encourage full and frank disclosure to the doctor. The law protects the patient's secrets and makes it the duty of the doctor to keep them, a duty he cannot waive. The veil of secrecy can be drawn aside only

by the patient or by ‘the presiding judge of a superior court’, and by him only when the ends of justice require it.

Yow v. Pittman, 241 N.C. 69, 70-71, 84 S.E.2d 297, 298 (1954). To that end, the North Carolina Supreme Court, when construing an earlier version of the statute, recognized that disclosure of health information by court order rather than a patient’s authorization was intended to occur in extremely limited circumstances: “The sole purpose of the 1885 statute ... now codified as G.S. s 8-53, was to create a privileged relationship between physician and patient. In view of this primary purpose, we think it clear the proviso was intended to refer to exceptional rather than ordinary factual situations.” *Lockwood v. MsCaskill*, 261 N.C. 754, 758, 136 S.E.2d 67, 69-70 (1964) (emphasis added). The requirement that disclosure be compelled only in rare circumstances is essential because once a provider is “required to testify concerning privileged matters ..., eo instante the statutory privilege is destroyed.” *Id.* at 757, 136 S.E.2d at 69.

Further, North Carolina’s Department of Health and Human Services has reinforced the requirement that a health care provider maintain its patients’ medical information in strict confidence by requiring the confidentiality of medical records as part of the licensing requirements for providers. *See* 10A N.C.A.C. 13C.1002(b) (2013) (mandating that the administrator of an ambulatory surgical facility “shall be responsible for safeguarding information on the medical record against loss, tampering, or use by unauthorized persons”); 10A N.C.A.C. 13B.3302(4) (recognizing a patient right to having “all records pertaining to his medical care treated as confidential” as part of the hospital licensure regulations).

Patients who are not parties to this MDL have not asked to be made parties or agreed to have their highly personal and sensitive protected health information disclosed to persons unknown to them for purposes entirely unrelated to their medical care. As the privilege belongs

to the patients alone, High Point Surgery Center cannot waive it for them and cannot disclose their medical information without a court order finding the PSC's request so exceptional that the disclosure is necessary for the administration of justice.

B. The PSC Requests Irrelevant, Confidential Medical Information that is Not Necessary for the Administration of Justice, and Discovery Must Be Denied to Prevent Unwarranted Intrusion into Non-party Patients' Privacy.

The PSC cannot meet its burden to show its need for the identities and other medical information of non-party patients is so exceptional that it is necessary for the administration of justice and overrides the rights of those patients. As previously stated, the records and information sought belong to non-party patients whose purported harms are not at issue in this MDL. The Bankruptcy Court is, upon High Point Surgery Center's information and belief, facilitating the notification of potential claimants, including non-party patients, in NECP's bankruptcy action and ensuring that those potential claimants receive sufficient notice prior to the bar date. High Point Surgery Center is not a party, and the PSC is requesting health information for patients who are not parties to an action pending in the MDL. The identities and other confidential medical information of non-parties have no bearing on the claims and defenses pending in this MDL, which centers on the harm to the Plaintiffs who have brought suit.

Although the PSC may argue it would be convenient and practical for Plaintiffs to obtain the confidential health information of non-party patients to ascertain additional claimants, Plaintiffs' "need" for such information is limited to the confines of legal "relevance." As the identities and other confidential medical information of non-parties are irrelevant to this litigation, the discovery of such information must be denied to protect non-party patients from the PSC's intrusion of their privacy. Moreover, the PSC's asserted "need" for this information

hardly amounts to the level of exceptional circumstances and necessity for which North Carolina allows the disclosure of information otherwise protected by the physician-patient privilege.

CONCLUSION

Along with HIPAA and the Federal Rules of Civil Procedure, North Carolina law prohibits the PSC from discovering the confidential medical information of non-party patients. The identities of non-party patients who were treated by a non-party healthcare provider are wholly irrelevant to the parties' claims and defenses pending in this MDL, and this Court should protect High Point Surgery Center's non-party patients from the PSC's intrusion of their right to privacy. Further, the PSC's intended use of protected health information, to notice non-party patients and ascertain other potential plaintiffs and defendants, is in violation of HIPAA, Rule 26(b)(1), and North Carolina law. As a result, pursuant to Rule 45, this Court is required to modify the PSC's Subpoena to the extent it requests confidential and protected health information of High Point Surgery Center's non-party patients.

This the 26th day of July, 2013.

/s/ Carrie A. Hanger
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CERTIFICATE OF SERVICE

This will certify that a true and accurate copy of the foregoing was served on all parties hereto by virtue of the Court's electronic filing system this 26th day of July, 2013.

/s/ Carrie A. Hanger
Carrie A. Hanger
Attorney for High Point Surgery Center